Lisa N Franklin

From:	MaryTherese Kocevar
Sent:	Wednesday, May 02, 2018 3:20 PM
To:	Lisa N Franklin
Subject:	FW: Request from Bryan Pesta for access to NIH controlled-access datasets

Please create an e-files folder to save this email and the signed document for future reference.
Thanks,
Teri

Sincerely,
Teri Kocevar, CRA
Director, Sponsored Programs & Research Services
Cleveland State University
2121 Euclid Avenue
Cleveland, Ohio 44115-2214
Phone: (216)687-3675

From: MaryTherese Kocevar
Sent: Wednesday, May 02, 2018 3:19 PM
To: Lisa N Franklin <l.franklin@csuohio.edu>
Cc: Bryan J Pesta <b.pesta@csuohio.edu>
Subject: FW: Request from Bryan Pesta for access to NIH controlled-access datasets

Lisa,
Please go ahead and approve/sign as required
Thanks!
Teri

Sincerely,
Teri Kocevar, CRA
Director, Sponsored Programs & Research Services
Cleveland State University
2121 Euclid Avenue
Cleveland, Ohio 44115-2214
Phone: (216)687-3675

From: Bryan J Pesta
Sent: Wednesday, April 18, 2018 2:54 PM
To: MaryTherese Kocevar <m.kocevar@csuohio.edu>
Subject: Re: Request from Bryan Pesta for access to NIH controlled-access datasets

Hi Mary,

Thanks for your help here.

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My replies:

1. I must submit the summary and RUS along with the dbGaP application. As per their policy, "if access is approved, you agree that the RUS along with your name and institution, will be included on the dbGaP website to describe your research project to the public". So, the research statement will be posted on the dbGaP website. If it needs to be posted elsewhere too (i.e., if anyone else at CSU has secured access to data like these, I'm happy to post wherever they did).

2. I have zero intent to identify or contact participants. Moreover, the data set I am applying for does not require IRB approval. See "Use Restrictions":

https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000607.v2.p2

Neurodevelopmental Genomics: Trajectories of Complex ...

www.ncbi.nlm.nih.gov

This study is a collaboration between the Center for Applied Genomics (CAG) at Children's Hospital of Philadelphia (CHOP) and the Brain Behavior Laboratory at the University of Pennsylvania (Penn). The cohort consists of youths aged 8-21 years who consulted the CHOP network and volunteered to ...

3. The phenotypic data are already publically available at ftp://ftp.ncbi.nlm.nih.gov/dbgap/studies/phs000607 . I have no plan for storing this publically available data. Conversely, I will be the only one who has access to data files which are restricted access, including genotypic data. I will store these data on my CSU computer only, which is password and firewall protected. Finally, I will destroy the restricted data after the analysis is completed.

4. I will be the only one who has access to these data. They will be stored on my CSU computer, which is password and firewall protected.

Please let me know if there are any more questions, and thanks again for your assistance.

Bryan

1. Public posting of the user's research use statement;
   a. Where would you post this information
2. Not to identify or contact individual participants without specific IRB approval;

   a. Have you received IRB approval yet?
3. Keep the data secure and confidential at all times;

   a. Where do you plan to secure the data? Who will have access to it?
4. Adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to NIH genomic datasets; and

   a. Again who will have access to the database and how will you ensure no one else can access it?

From: MaryTherese Kocevar
Sent: Tuesday, April 17, 2018 11:59:53 AM
To: Bryan J Pesta
Subject: FW: Request from Bryan Pesta for access to NIH controlled-access datasets

Bryan,

I spoke with our legal counsel, Jack Kraszewski, regarding approving this. I need to gather some more information before I can approve. Please advise to the following:

1. Public posting of the user's research use statement;
    a. Where would you post this information
2. Not to identify or contact individual participants without specific IRB approval;

    a. Have you received IRB approval yet?
3. Keep the data secure and confidential at all times;

    a. Where do you plan to secure the data? Who will have access to it?
4. Adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to NIH genomic datasets; and

    a. Again who will have access to the database and how will you ensure no one else can access it?

Thank you.
Teri

Sincerely,
Teri Kocevar, CRA
Director, Sponsored Programs & Research Services
Cleveland State University
2121 Euclid Avenue
Cleveland, Ohio 44115-2214
Phone: (216)687-3675

From: Jack N Kraszewski
Sent: Friday, April 13, 2018 11:32 AM
To: Lisa N Franklin <l.franklin@csuohio.edu>
Subject: RE: Request from Bryan Pesta for access to NIH controlled-access datasets

Lisa,

This DAC places a number of conditions and requirements on the PI, and ultimately on the University since it clearly requires that University admin review and approve the DAC and the PI's agreement to the conditions and requirements. The DAC specifically requires:

By signing the Data Use Certificate, investigators are agreeing to:

- The terms of access and user responsibilities specified in the Data Use Certificate;
- Public posting of the user's research use statement;
- Not to identify or contact individual participants without specific IRB approval;
- Retain control of the data and not to distribute the data to any entity or individual not covered in the Data Access Request;
- Handle the requested dataset(s) according to the current dbGaP Security Best Practices;
- Keep the data secure and confidential at all times;
- Adhere to information technology practices in all aspects of data management to assure that only authorized individuals can gain access to NIH genomic datasets; and
- Notify the appropriate Data Access Committee (DAC) of any unauthorized data sharing, breaches of data security, violations in the presentation and publication embargo period, or inadvertent data releases that may compromise data confidentiality within 24 hours of when the incident is identified.

Dr. Pesta may also need IRB approval as provided in the DAC: "By approving and submitting the attached DAR, the Institutional Signing Official provides assurance that relevant institutional policies and national, tribal, and state laws and regulations, as applicable, have been followed, including IRB approval if required. The Institutional Signing Official also assures through the approval of the DAR that other institutional departments with relevant authorities (e.g., those overseeing human subjects research, information technology, or technology transfer) have reviewed the relevant sections of the NIH GDS Policy and the associated procedures and are in agreement with the principles defined."

Without knowing what steps Dr. Pesta to comply with the requirements and conditions, and whether or not IRB approval is required, I cannot approve this DAC.

Regards,
Jack

Jack N. Kraszewski
Director, Technology Transfer Office
Assistant Attorney General
Cleveland State University
2258 Euclid Ave., PH 214
Cleveland, OH 44115
(O) 216-687-5108

From: Lisa N Franklin
Sent: Thursday, April 12, 2018 3:37 PM
To: Jack N Kraszewski
Subject: FW: Request from Bryan Pesta for access to NIH controlled-access datasets

Hi Jack,
Teri said I should run this by you. Please see email below. Should I approve this?
Thanks,
Lisa

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From: dbgap-reply@ncbi.nlm.nih.gov [mailto:dbgap-reply@ncbi.nlm.nih.gov]
Sent: Thursday, April 12, 2018 11:01 AM
To: Lisa N Franklin <l.franklin@csuohio.edu>
Subject: Request from Bryan Pesta for access to NIH controlled-access datasets

This is an automated message from NCBI dbGaP (the Database of Genotypes and Phenotypes) Authorized Access system. Do not reply back to this message or send email to dbgap-reply@ncbi.nlm.nih.gov

Dear Lisa Franklin,

Bryan Pesta has initiated a request in project #18007: "Sex differences in cortical volume and g in a large adolescent sample" for access to datasets requiring that the Requester and her/his institution abide by the terms and conditions for data use as specified in one or more Data Use Certifications (DUC). Please click on the links below to review these documents.

Data Use Certifications for this Request

- Neurodevelopmental Genomics: Trajectories of Complex Phenotypes

The Requester has certified agreement to the terms by submission of this data access request. Bryan Pesta has listed you as an authorized institutional signing official for CLEVELAND STATE UNIVERSITY. Your approval of the request signifies agreement by your organization to the terms and conditions specified in the DUC(s) listed above, and is required by NCBI dbGaP prior to consideration of the request.

NCBI dbGaP Project Datasets distributed under this certification process will be coded to protect the identity of research participants. However, due to the personal nature of genomic sequence data and, in some cases, associated phenotype data, it may be possible in principle to use the data to identify an individual participant. Thus, such data types will only be provided to investigators who, along with their institutions, have certified their agreement with the requirements and terms of access specified in the DUC. If you would like more information on specific participant protection policies and data sets, please visit

- Neurodevelopmental Genomics: Trajectories of Complex Phenotypes: http://grants.nih.gov/grants/gwas

Note that the Data Access Request web form submitted by Bryan Pesta utilizes the grant application template solely to collect information about the Requester and his/her organization. This is not a grant application and no funds are associated with this request.

Please review and evaluate the data access request (click here). You will be required to enter a valid NIH electronic Research Administration (eRA) User ID (LNFRANKLIN) and password to review the Data Access Request. Please review the content of the request by clicking on "Submission overview". If you agree to the terms and conditions for data use as specified in the DUC(s) and wish to approve the request, check both of the boxes on the "Review Applications" web page, then click on the "Approve and submit to DAC" button to forward the completed request to the NIH dbGaP Data Access Committee (DAC) for consideration.

If you are unable to login to dbGaP you likely need to reset your eRA Commons password as they expire every six months: https://public.era.nih.gov/commons/ Note that you can log in to dbGaP and renew or close projects even if you have been suspended (suspension pertains to downloading data and submitting new requests only).

For Signing Officials (SOs): A new resource for institutional oversight of dbGaP projects is available. Any institutional SO who has used dbGaP can now download spreadsheets with up-to-date status information for ALL past and present dbGaP projects at your institution. Login to your dbGaP account and look for the links at the bottom of the "Signing Official's Projects" page.

If you have any questions or concerns regarding the data access certification, the DAC(s) responsible for processing this request can be contacted by email to

- Neurodevelopmental Genomics: Trajectories of Complex Phenotypes: JAAMHDAC@mail.nih.gov

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If you have any questions regarding Authorized Access Portal please contact the NCBI dbGaP <u>Help Desk</u>. Please do not reply to this message.